PRESSURE TRANSMISSION CATHETERS FOR IMPLANTABLE PRESSURE SENSORS

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] This application is a continuation in part of U.S. Patent Application Serial No. 10/077,566, filed February 15, 2002, entitled Devices, Systems and Methods for Endocardial Pressure Measurement, and claims priority to U.S. Provisional Application No. 60/454,823, filed March 12, 2003, entitled Pressure Transmission Catheters For Implantable Pressure Sensors, the entire disclosures of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

Field of the Invention

[0002] The present invention relates to implantable pressure sensing devices that utilize a catheter to transmit pressure from a measurement site to a pressure transducer.

[0003] An example of an implantable pressure sensing device is disclosed in U.S. Patent No. 4,846,191 to Brockway et al. Such an implantable pressure sensing device utilizes a fluid-filled catheter to refer pressure from a measurement site to a pressure sensor.

[0004] Depending on many different factors including the nature of the tissue through which the catheter extends and the environment in which the distal end of the catheter resides, it may be desirable to select a catheter design that suits the particular clinical application.

BRIEF SUMMARY OF THE INVENTION

[0005] To address this need, the present invention provides a variety of catheter designs to address different clinical situations. These catheter designs are particularly suited for use in combination with implantable pressure sensing devices. Each of the catheter features disclosed herein may be used alone or in combination with other features, and thus there are numerous different catheter design options, exemplary embodiments of which are described in more detail hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

[0006] Figure 1 is a schematic plan view of pressure monitoring system utilizing an implantable telemetry device, which includes a remote sensor assembly having a pressure transmission catheter disposed endocardially;

[0007] Figure 2 is a schematic view illustrating various possible endocardial implant locations for the remote sensor assembly;

[0008] Figure 3 is a schematic view of the remote sensor assembly including a first embodiment of the pressure transmission catheter shown in longitudinal cross-section;

[0009] Figures 4A – 4E are schematic side views of various alternative embodiments of the pressure transmission catheter, particularly illustrating various surface modifications thereof;

[0010] Figures 5A – 5W are schematic illustrations of a wide variety of alternative embodiments of the pressure transmission catheter shown in longitudinal cross-section;

[0011] Figures 6A – 6D are schematic illustrations of various cross-sectional geometries of the lumen extending through the pressure transmission catheter shown in lateral cross-section;

[0012] Figures 7A – 7E and 8 illustrate various tools that may be employed to insert the pressure transmission catheter through bodily tissue; and

[0013] Figures 9 – 11 illustrate a mathematical model of the pressure transmission catheter.

DETAILED DESCRIPTION OF THE INVENTION

[0014] The following detailed description should be read with reference to the drawings in which similar elements in different drawings are numbered the same. The drawings, which are not necessarily to scale, depict illustrative embodiments and are not intended to limit the scope of the invention.

[0015] With reference to Figure 1, an exemplary embodiment of a system 10 for measuring and monitoring endocardial pressure is shown. The system 10 includes an implantable telemetry device (ITD) 20, which may be partitioned into a remote sensor assembly (RSA) 30 and a telemetry unit (TU) 40 interconnected via lead 50. An

alternative construction (not shown) of the ITD 20 mounts the RSA 30 and TU 40 components in a single unit which may be implanted in a manner similar to RSA 30. The RSA 30 measures endocardial pressure and the TU 40 transmits measured pressure data to a receiver located outside the body via wireless telemetry link 80.

[0016] The system 10 also includes a home (i.e., local) data collection system (HDCS) 60 which receives the telemetry signal from the TU 40 via wireless link 80. The TU 40 may correct for fluctuations in ambient barometric pressure, may evaluate the validity of the received signal, and, if the received signal is deemed to be valid, may extract parameters from that signal and store the data according to a physician-defined protocol.

[0017] The system 10 further includes a physician (i.e., remote) data collection system (PDCS) 70 which receives the data signal from the HDCS 60 via a telecommunication link 90 (e.g., the Internet). The PDCS 70 may evaluate the validity of the received signal and, if the received signal is deemed to be valid, may display the data, and store the data according to a physician-defined protocol. With this information, the system 10 enables the treating physician to monitor endocardial pressure in order to select and/or modify therapies for the patient to better treat diseases such as CHF and its underlying causes.

[0018] For example, the system 10 may be used for assessment of pressure changes (e.g., systolic, diastolic, min dP/dt, and max dP/dt) in the main cardiac pumping chamber, the left ventricle (LV). These pressures are known to fluctuate with clinical status in CHF patients, and they provide key indicators for adjusting treatment regimens. For example, increases in end-diastolic pressure, changes in the characteristics of pressure within the diastolic portion of the pressure waveform, and decreases in max dP/dt, or increases in minimum dP/dt together suggest a deteriorating cardiac status. With this information, the physician is able to promptly and remotely adjust treatment. In addition, the system 10 may assist the physician in management of patients when newer forms of device therapy (e.g., multiple-site pacing, ventricular assist as a bridge to recovery, or implantable drugs pumps) are being considered.

[0019] The RSA 30 includes a pressure transducer 39 (visible in Figure 3) and an electronics module (not visible) contained within a housing 32. The pressure transducer 39 and the electronics module may be the same or similar to those described in U.S. Patent Nos. 4,846,191, 6,033,366, 6,296,615 or PCT Publication WO 00/16686, all to Brockway et al., the entire disclosures of which are incorporated herein by reference. The RSA

housing 32 protects the pressure transducer 39 and the electronics module from the harsh environment of the human body. The RSA housing 32 may be fabricated of a suitable biocompatible material such as titanium or ceramic and may be hermetically sealed.

[0020] The pressure transducer 39 may be of the piezoresistive, resonant structure, or capacitive type. For example, the pressure transducer may comprise a piezoresistive Wheatstone bridge type silicon strain gauge available from Sensonor of Horton, Norway. Examples of suitable pressure transducers are disclosed in U.S. Patent Application Serial No. 10/717,179, filed November 17, 2003, entitled Implantable Pressure Sensors, the entire disclosure of which is incorporated herein by reference. The electronics module may provide excitation to the pressure transducer 39, amplify the pressure and EGM signals, and digitally code the pressure and EGM information for communication to the TU 40 via the flexible lead 50. The electronics module may also provide for temperature compensation of the pressure transducer 39 and provide a calibrated pressure signal. A temperature measurement device may be included within the electronics module to compensate the pressure signal from temperature variations.

[0021] The proximal end of the RSA housing 32 includes an electrical feedthrough to facilitate connection of the electronics module to the flexible lead 50. The distal bottom side of the housing includes a pressure transducer header to facilitate mounting of the pressure transducer and to facilitate connection to a pressure transmission catheter (PTC) 34.

[0022] The flexible lead 50 connects the electronics module of the RSA 30 to the telemetry electronics disposed in the TU 40. The lead 50 may contain, for example, four conductors - one each for power, ground, control in, and data out. The lead 50 may incorporate conventional lead design aspects as used in the field of pacing and implantable defibrillator leads. The lead 50 may optionally include one or more EGM electrodes, and the number of conductors may be modified to accommodate the EGM electrodes.

[0023] The TU 40 includes telemetry electronics (not visible) contained within housing 42. The telemetry electronics disposed in the TU 40 may be the same or similar to those described in U.S. Patent Nos. 4,846,191, 6,033,366, 6,296,615 or PCT Publication WO 00/16686, all to Brockway et al. The TU housing 42 protects the telemetry electronics from the harsh environment of the human body. The TU housing 42 may be fabricated of a suitable biocompatible material such as titanium, ceramic, or a combination thereof, and

is hermetically sealed. Examples of other suitable housing designs are disclosed in U.S. Provisional Patent Application No. 60/438,712, filed January 7, 2003, entitled Housing For Implantable Telemetry Device, the entire disclosure of which is incorporated herein by reference. The outer surface of conductive (i.e., metallic) portions of the TU housing 42 may serve as an EGM sensing electrode. If a non-conductive material such as ceramic is used for the housing 42, conductive metal pads may be attached to the surface thereof to serve as EGM sensing electrodes. The TU housing 42 includes an electrical feedthrough to facilitate connection of the telemetry electronics to the lead 50.

[0024] The PTC 34 refers pressure from the pressure measurement site to the pressure transducer 39 located inside the RSA housing 32. The PTC 34 may comprise a tubular structure with a liquid-filled lumen extending therethrough to a distal opening or port. Various constructions of the PTC 34 are described in more detail hereinafter. The PTC 34 may optionally include one or more EGM electrodes or other physiological sensors as described in U.S. Patent No. 6,296,615 to Brockway et al.

[0025] The proximal end of the PTC 34 is connected to the pressure transducer via a nipple tube (visible in Figure 3), thus establishing a fluid path from the pressure transducer to the distal end of the PTC 34. A barrier such as a gel plug and/or membrane may be disposed in or over the distal opening to isolate the liquid-filled lumen of the PTC 34 from bodily fluids and to retain the fluid in the lumen, without impeding pressure transmission therethrough. In one embodiment, the fluid is chosen to be a fluorinated silicone oil and the gel is chosen to be dimethyl silicone gel. Further aspects of suitable fluids and gels are described in U.S. Patent Application Serial No. 10/272,489, filed October 15, 2002, entitled Improved Barriers and Methods for Pressure Measurement Catheters, the entire disclosure of which is incorporated herein by reference.

[0026] Further details and other aspects of the system 10 are described in U.S. Patent Application Serial No. 10/077,566, filed February 15, 2002, entitled Devices, Systems and Methods for Endocardial Pressure Measurement. Reference may also be made to U.S. Patent No. 4,846,191 to Brockway et al., U.S. Patent No. 6,033,366 to Brockway et al., U.S. Patent No. 6,296,615 to Brockway et al., and PCT Publication WO 00/16686 to Brockway et al. for examples of alternative embodiments.

[0027] As seen in Figure 1, the ITD 20 may be surgically implanted in/on a heart 100 of a patient. In this exemplary embodiment, the PTC 34 is inserted directly into the left

ventricle (LV) 102 across the left ventricular wall 130 for the purpose of measuring LV pressure. In particular, the RSA housing 32 resides on the epicardial surface 112 in the pericardial space defined by pericardium 120, with the PTC extending across the epicardium 112, myocardium 110 and endocardium 114, and into the LV chamber 102. This allows for chronic monitoring of pressure in the LV chamber 102 of the heart 100.

[0028] Implantation of the ITD 20, including RSA 30 and TU 40, may take place during an open chest procedure such as would normally be done to perform coronary artery bypass or valve repair/replacement. Alternatively, the ITD 20 may be implanted in a separate surgical procedure. In such a case, the surgeon performs a median sternotomy, cutting across the dermal layer 128, sub-dermal tissue layer 126, muscle layer 124, and sternum 122. The surgeon then cuts the pericardial sac 120 to expose the heart 100, down to the LV apex.

[0029] The PTC 34 is introduced into the LV 102 at the inferior apical segment using a peelable-sheath introducer 810 and a trocar 820 as shown in Figure 8. The peelable-sheath introducer 810 facilitates insertion of the PTC 34 into the myocardium 110 and protects the PTC 34 from damage that may otherwise occur during the insertion process. Following insertion of the PTC 34, the peelable-sheath introducer 810 is removed by peeling the introducer 810 off the PTC 34 and around the RSA housing 32. A sheath retainer 710 or 720 as shown in Figures 7A – 7D may be used to prevent splitting of the introducer 810 inside the heart wall and to hold the RSA 30 in place while the introducer 810 is removed. The PTC 34 is automatically positioned within the LV 102, in terms of depth, by virtue of its length when the housing 32 of the RSA 30 contacts the epicardial surface.

[0030] The proximal lead 50 is then draped over the open pericardial edge, and brought caudally inferior laterally under the abdominal fascia. A 4 – 5 cm horizontal incision is made on the left upper quadrant of the abdominal wall and a subcutaneous pocket is created. The proximal end of the flexible lead 50 may be brought into the subcutaneous pocket through an introducer placed through the abdominal fascia. If a releasable connection is utilized, the lead 50 is attached to the TU 40, tested using a PDCS, and the TU 40 is placed in the subcutaneous pocket. The pocket and the chest are then closed.

[0031] With reference to Figure 2, various possible anatomical implant positions for the RSA 30 are shown. To facilitate a discussion of the various possible anatomical implant

positions, the heart 100 is shown schematically. The heart 100 includes four chambers, including the left ventricle (LV) 102, the right ventricle (RV) 104, the left atrium (LA) 106, and the right atrium (RA) 108. The LV 102 is defined in part by LV wall 130, and the RV 104 is defined in part by RV wall 134. The LV 102 and the RV 104 are separated by ventricular septal wall 132, and the LA 106 and the RA 108 are separated by atrial septal wall 136.

[0032] The right atrium 108 receives oxygen deprived blood returning from the venous vasculature through the superior vena cava 116 and inferior vena cava 118. The right atrium 108 pumps blood into the right ventricle 104 through tricuspid valve 142. The right ventricle 104 pumps blood through the pulmonary valve and into the pulmonary artery which carries the blood to the lungs. After receiving oxygen in the lungs, the blood is returned to the left atrium 106 through the pulmonary veins. The left atrium 106 pumps oxygenated blood through the mitral valve 144 and into the left ventricle 102. The oxygenated blood in the left ventricle 102 is then pumped through the aortic valve, into the aorta 117, and throughout the body via the arterial vasculature.

[0033] By way of example, not limitation, the RSA 30 may be implanted such that the distal end of the PTC 34 resides in any chamber of the heart 100, such as the LV 102 or the LA 106, for example, although the LV 102 is preferred for some clinical applications. For example, the PTC 34 may be positioned across the LV wall 130 such that the distal end of the PTC 34 is disposed in the LV 102 as described with reference to Figure 1. As an alternative, the PTC 34 may be positioned across the RV wall 134 such that the distal end of the PTC 34 is disposed in the RV 104. As a further alternative, the PTC 34 may be positioned across the atrial septal wall 136 or the ventricular septal wall 132 such that the distal end of the PTC 34 is disposed in the LA 106 or LV 102, respectively. If the ITD 20 comprises a unitary structure containing both the RSA 30 and the TU 40, the ITD 20 may be positioned in the same manner as the RSA 30 or it may be entirely disposed within a heart chamber.

[0034] Although endocardial implant sites are shown and described herein, the RSA 30 may be implanted such that the PTC 34 extends through a vascular wall and into a vascular lumen, with the RSA housing 32 and associated components disposed outside the vascular wall. Further aspects of this vascular approach are described in U.S. Provisional Patent Application No. 60/440,151, filed January 15, 2003, entitled Therapeutic Device

and Method Using Feedback from Implantable Sensor Device, the entire disclosure of which is incorporated herein by reference.

[0035] With reference to Figure 3, further details of the PTC 34 are shown schematically. In Figure 3, the PTC 34 is shown in longitudinal cross-section with its proximal end connected to the RSA 30. The PTC 34 may comprise a tubular shaft 22 with a liquid-filled lumen 24 extending therethrough to a distal opening or port 36 containing a barrier plug 26. The proximal end of the PTC 34 is connected to the pressure transducer 39 in the RSA 30 via nipple tube 38. The PTC 34 refers pressure from the distal port 36 via plug 26 and liquid-filled lumen 24 to the pressure transducer 39 of the RSA 30 via a lumen extending through nipple tube 38.

[0036] The proximal end of the PTC 34 may include an interlocking feature to secure the PTC 34 to the nipple tube 38. For example, the nipple tube may have an enlarged head as shown, or may have a knurled surface, raised rings or grooves, etc. A compression band 37 may be disposed around the proximal end of the PTC 34 to provide compression onto the interlocking feature of the nipple tube 38. The compression band 37 may comprise a polymeric or metallic (e.g., shape memory NiTi) band, a spring coil, etc., to provide compression onto the nipple tube 38.

[0037] The PTC 34 may comprise a wide variety of materials, constructions and dimensions depending on the particular clinical application and the bodily tissue in which the PTC 34 resides when implanted. For example, the PTC 34 may comprise an extruded polyurethane (e.g., Bionate™) tube with a thermally formed proximal flare to accommodate the nipple tube 38, and a thermally formed distal flare to reduce pressure measurement errors due to motion artifacts and thermal expansion artifacts. The PTC 34 may also incorporate a polyester fabric tube 33 or other surface modification. The PTC 34 may be annealed to improve its mechanical properties and may be etched in solvent to remove frayed edges. Various materials and construction alternatives for the PTC 34 are described in more detail hereinafter.

[0038] By way of example, not limitation, in each of the embodiments described herein, the PTC 34 may have an overall length of approximately 26 mm, a proximal flare length of approximately 6.0 mm, a distal flare length of approximately 5.5 mm, tapered transition lengths of approximately 2.0 mm, a mid-shaft inside diameter of approximately 0.025 inches, a proximal flare inside diameter of approximately 0.038 inches increasing to 0.059

inches to accommodate the nipple tube 38, a distal flare inside diameter of approximately 0.042 inches, and a wall thickness of approximately 0.015 inches, which are particularly suitable for LV pressure monitoring applications as shown and described with reference to Figure 1. Various different lengths, diameters, tapers, flares, wall thicknesses, coatings, coverings, surface treatments, etc. may be incorporated into the PTC 34 depending on the application without departure from the present invention.

[0039] With reference to Figures 4A – 4E, a portion 35 of the PTC 34 may be modified to promote tissue in-growth, to prevent migration of infectious contaminants, to improve the seal between the PTC 34 and the surrounding tissue, and to improve anchoring. Such modifications 35 may also be applied to the lead 50 for similar effect. The modification 35 may be applied to portions of the PTC 34 that come into contact with tissue, such as a proximal portion of the PTC 34. Those skilled in the art will recognize that the modified portion 35 may be applied to all, a portion, or a combination of portions of the PTC 34. For example, in addition or in the alternative to a proximal portion, a distal portion of the PTC 34 may be modified to promote endothelialization and reduce thrombogenicity at the blood interface. The modification may comprise a surface modification of the tubular shaft 22 itself, and/or additional material may be disposed on the outer surface of the tubular shaft 22.

[0040] For example, as seen in Figure 4A, the modified portion 35 may comprise a PET, polyester, ePTFE, or PU layer. Alternatively, the material added to the modified portion 35 of the outer surface of the tubular shaft 22 may comprise a biodegradable matrix of PLA, PGA, PHB, collagen, etc. The modified portion 35 may be deposited, woven, spun, knit, coated, slid over, or otherwise disposed onto the outer surface of the tubular shaft 22.

[0041] For example, the modified portion 35 may comprise a separate tube slid onto the tubular shaft 22 of the PTC 34, such as the polyester fabric tube 33 described with reference to Figure 3. In this embodiment, the polyester fabric tube 33 may be bonded at one or more of its ends to the tubular shaft 22 utilizing a solvent bond (e.g., polyurethane mixed with solvent) that bonds with the material of the tubular shaft 22 and wicks into the polyester fabric tube 33. This creates a smooth transition from the fabric tube 33 to the tubular shaft 22 to reduce thrombus formation, tissue erosion, etc., at the tissue interface. To reduce movement between the device-tissue interface, one end of the fabric tube 33 may be bonded to the tubular shaft 22, while the other end remains free, thus reducing

movement between the fabric tube 33 and the tissue in favor of movement between the fabric tube 33 and the tubular shaft 22. In addition or in the alternative, the fabric tube 33 may incorporate slack or bellows as shown in Figure 4B to further minimize movement at the device-tissue interface.

[0042] As seen in Figure 4C, the modified portion 35 may comprise texturing of the outer surface of the tubular shaft 22 by chemical etching, thermal pre-forming or re-forming (e.g., by extrusion, molding, casting, etc.), for example.

[0043] As seen in Figure 4D, the modified portion 35 may comprise a material that swells after exposure to bodily fluids. For example, the modified portion 35 may comprise an outer layer of hydrophilic material that swells upon exposure to water based fluids. After the PTC 34 is inserted through the heart wall or other tissue, the modified portion 35 expands radially to create a tight fit between the PTC 34 and the surrounding tissue. This feature reduces the likelihood of bleeding, thrombus formation, and migration of foreign substances into the endocardial space.

[0044] As seen in Figure 4E, when a metallic tubular shaft 22 is utilized for the PTC 34, the modified portion 35 may comprise sintered spheres applied to the metal tubular shaft 22 or a surface modification of the metal tubular shaft 22 such as pickling, pitting, abrasive roughening, etc.

[0045] The modified portion 35 may be loaded with steroid, anticoagulant, or a first part of a two part fibrin promoting agent (with the second part being disposed on the sheath used to introduce the PTC 34 into the heart wall). The loaded agent may elute over time into the surrounding tissue to promote healing and to minimize thrombus formation.

[0046] With reference to Figures 5A – 5W, various embodiments of the PTC 34 are shown in longitudinal cross-section. The embodiments illustrated in Figures 5A – 5R are shown schematically and are not necessarily to scale. Aspects of each embodiment may be taken alone or in combination, and are described by way of example, not limitation. The various modifications described with reference to Figures 3 and 4A – 4E may be employed with any of the embodiments described with reference to Figures 5A – 5W.

[0047] In Figure 5A, the PTC 34 comprises a tubular shaft 22 defining a fluid-filled lumen 24 therein extending to a distal facing port 36 having a gel plug 26 disposed therein.

In Figure 5A the gel plug 26 is flush with the distal end of the PTC 34, whereas in Figure 5B, the gel plug 26 is slightly recessed from the distal end of the PTC 34.

[0048] The opening 36 may face distally at the distal end of the PTC 34 as shown in Figure 5A for example, or the opening 36 may face laterally as shown in Figure 5C, for example. In Figure 5C, the PTC 34 includes a lateral facing port 36 filled with barrier material 26. In Figure 5D, two lateral ports 36 are provided, and in Figure 5E, a single lateral port in combination with a distal facing port 36 are provided on the PTC 34.

[0049] The port(s) 36 may have the same cross-sectional area as the fluid-filled lumen 24, or the port(s) 36 may have a larger surface area (i.e., flared) than the lumen 24 of the PTC 34. As may be appreciated by comparing the embodiments illustrated in Figures 5D and 5G, lateral facing ports 36 may have a larger cross-sectional area than the lumen 24 without the need to provide a flared end as shown n Figure 5A. An enlarged (e.g., flared) opening 36 reduces movement of the plug 26 during events that change either the volume of the transmission fluid or the internal volume of lumen 24, such as occurs during thermal expansion and contraction, bending, and hydration of the catheter material of PTC 34. Reducing the degree of displacement of plug 26 during bending of PTC 34 has the effect of reducing measurement artifact that can occur during normal movement of the subject into which the RSA 30 is implanted. Reducing the degree of displacement of plug 26 during bending of PTC 34 reduces the maximum amount of dead space (space defined by recessed plug 26 as seen in Figure 5B) within PTC 34 and beyond plug 26, and therefore, contributes to improved patency in blood. Moreover, the larger surface area of the opening(s) 36 also increases the frequency response of the device.

[0050] As seen in Figure 5A, the proximal and distal ends of the PTC 34 may be flared to have a larger inside diameter (ID) and outside diameter (OD), for different purposes. The distal end of the PTC 34 may be flared to provide an opening 36 having a larger surface area as discussed above, and the proximal end of the PTC 34 may be flared to accommodate the nipple tube (not shown) and provide a compression fit thereon. The proximal flared portion may have an ID that is smaller than the nipple tube to provide a compression fit that will be stable for the life of the RSA 30.

[0051] The mid portion or stem of the PTC 34 may have a smaller ID/OD, with gradual transitions between the stem and the flared ends. The gradual transitions in diameter provide gradual transitions in stiffness to thereby avoid stress concentration points, in

addition to providing a more gradual funneling of the gel into the stem in the event of thermal retraction. The unitary one-piece construction of the PTC 34 may also provide a more robust and reliable construction than multiple piece constructions. Absent the gradual transitions, the PTC 34 may be more susceptible to stress concentration points, and the gel and the transmission fluid are more likely to become intermixed and may potentially dampen pressure transmission.

[0052] By way of example, not limitation, the proximal flared portion may have an ID of 0.026 inches, an OD of 0.055 inches, and a length of about 7 mm. The stem (mid) portion may have an ID of 0.015 inches, and OD of 0.045 inches, and a length of about 7 mm. The distal flared portion may have an ID of 0.035 inches, an OD of 0.055 inches, and a length of about 4 to 5 mm. The proximal taper may have a length of about 0.5 mm and the distal taper may have a length of about 1.25 mm. The gel plug 26 may have a length of about 3 mm and resides in the distal flared portion.

[0053] In cases where a relatively short PTC 34 is utilized, the fluid-filled lumen 24 of the PTC 34 may be completely filled with the barrier material 26 (e.g., gel) as shown in Figure 5F, for example. In combination with the gel plug 26, or in place thereof, a thin membrane 28 may be disposed over the port(s) 36. For example, as shown in Figure 5H, a thin membrane material 28 is disposed over the lateral ports 36. As shown in Figure 5I, a thin membrane material 28 is disposed over the distal facing opening 36. The thin membrane material 28 may comprise a thin, biocompatible polymeric material.

[0054] The PTC 34 should have a length sufficient to extend across a myocardial wall and into a heart chamber. For example, the proximal portion of PTC shaft 34 may have a length of about 10 – 15 mm, and the distal portion of PTC shaft 34 may have a length of about 2 – 15 mm. The PTC 34 preferably has a length that provides adequate access across the myocardium and into the left ventricle while being as short as possible to minimize head height effects associated with the fluid-filled lumen 24. The PTC 34 may be straight or may be curved, depending on the particular orientation of the RSA 30 relative to the heart wall and the chamber defined therein at the insertion point. An anti-thrombogenic coating may be applied to the distal portion of PTC shaft 34, and the proximal portion of PTC shaft 34 may be over-molded with silicone to provide stress relief, flex fatigue strength, and a compliance matching mechanism at the entrance to the myocardium.

[0055] The PTC 34 may be positioned across a heart wall, with the proximal portion of PTC shaft 34 extending across myocardium 110 and the distal portion of PTC shaft 34 disposed endocardially, as schematically shown in Figure 1. The proximal portion of the PTC shaft 34 extends across the entire myocardial wall 110, from the exterior myocardial surface or epicardium 112, to the interior myocardial surface or endocardium 114. Optionally, the proximal portion of PTC shaft 34 may extend across the pericardium, epicardium and myocardium. Because the heart walls are dynamic structures subject to expansion and contraction, the proximal portion of PTC shaft 34 may be made relatively crush-resistant, with sufficient crush resistance to prevent collapse caused by myocardial contraction. The distal portion of PTC shaft 34 may be made relatively flexible with radiused corners to provide an atraumatic tip.

[0056] For example, as seen in Figure 5J, the PTC 34 may comprise a stainless steel or titanium hypotube shaft 22B (e.g., an extension of the nipple tube) extending through the proximal (myocardial) portion of the PTC shaft 34, with a polymeric tubular shaft 22A extending over and beyond the hypotube shaft 22B into the distal (endocardial) portion of the PTC shaft 34. Alternatively, the proximal portion of PTC shaft 34 may be formed of a polymeric material having a relatively high durometer and the distal portion of PTC shaft 34 may be formed of a polymeric material having a relatively low durometer. The proximal and distal portions of the PTC shaft 34 may be formed of separate tubes connected together, or by a single tube with a gradient stiffness, such as provided by interrupted layer coextrusion processes. As a further alternative, the proximal portion of PTC shaft 34 and the distal portion of PTC shaft 34 may comprise a polymeric tube having a relatively low durometer, with a rigid polymeric sleeve having a relatively high durometer extending over the proximal portion of PTC shaft 34.

[0057] In some embodiments, particularly in transluminal embodiments as described in U.S. Patent Application Serial No. 10/077,566, filed February 15, 2002, entitled Devices, Systems and Methods for Endocardial Pressure Measurement, the distal tip of the PTC 34 may be used to puncture the heart wall. In such instances, it may be desirable to provide additional column strength to the PTC 34 to avoid buckling penetrating the heart wall, such as may be provided by a metallic or composite tubular shaft 22 as described elsewhere herein. In addition, to avoid coring tissue as the distal tip of the PTC 34 punctures the heart wall, a dissolvable material 150 such as Manitol may be disposed in or around the opening 36 distal of the membrane or gel barrier 26 disposed therein. Once

implanted, the material 150 dissolves and pressure communication is reestablished with the opening 36.

[0058] Various configurations are possible with such a dissolvable material 150. For example, as seen in Figure 5K, the dissolvable material 150 may be disposed in opening 36 located in the side of PTC 34. In this embodiment, the distal tip of the PTC 34 may include a sharpened tip 29 to facilitate puncturing the heart wall. Alternatively, as seen in Figure 5L, the dissolvable material 150 may be disposed in opening 36 at the distal end of the PTC 34, and may define a sharpened tip 152 to ease puncturing the heart wall.

[0059] As yet another alternative to avoid coring, a special tip 160 having a sharpened tip 162 may be attached or formed onto the distal end of the PTC 34 as seen in Figure 5M. The tip 160 may be formed of a biocompatible material, or a dissolvable material such as Manitol, and may define a curved lumen filled with a gel barrier or plug 26 to provide a pressure referring path between the fluid-filled lumen 24 of the PTC 34 and the lateral-facing opening 36 of the tip 160. Because the opening 36 of the tip 160 faces laterally, the likelihood of coring cardiac tissue is reduced if not eliminated.

[0060] Alternative multi-layer embodiments of the PTC shaft 34 may also be employed, an example of which is shown in Figure 5N. Generally speaking, multi-layered or composite embodiments permit each layer of the PTC shaft 34 to be independently designed to serve a different purpose tailored to the desired functionality. For example, as shown in Figure 5N, the PTC shaft 34 comprises three layers, namely outer layer 22A, middle layer 22B, and outer layer 22C. Inner layer 22C may comprise a material that provides efficient pressure waveform transmission and high impermeability to bodily fluids such as polyurethane or polycarbonate-urethane (e.g., Bionate™). Middle layer 22B may comprise a material that is resistant to biodegradation and serves to bond or frictionally engage the inner layer 22C with the outer layer 22A such as silicone. The middle layer 22B may comprise a tube or may be applied as a suspension or coating on the outer surface of the inner layer 22C. The middle layer 22B may alternatively comprise an adhesive that is initially lubricious to facilitate mounting of the outer layer 22A over the inner layer 22C, and may be subsequently cured by thermal or light (e.g., UV) activation. Outer layer 22A may comprise a material that is biocompatible and promotes tissue in-growth (e.g., endothelialization) such as expanded PTFE (ePTFE). The distal end of the

inner layer 22C may be flared outwardly to enhance retention of the middle layer 22B and outer layer 22A.

[0061] With reference to Figures 5O and 5P, a metallic tubular shaft 22 may be employed for the PTC 34. The metallic tubular shaft 22 may comprise titanium, titanium alloy, stainless steel, or other suitable implantable metal or metal alloy. The inner surface of the metal tubular shaft 22 may be smooth to facilitate efficient pressure signal transmission and the outer surface of the metal tubular shaft 22 may be modified as discussed with reference to Figures 4A – 4E. The distal tip of the tubular shaft 22 may be cut to form a square tip as seen in Figure 5O, or swaged inward to form a tapered or well rounded tip as seen in Figure 5P, which may facilitate insertion through the heart wall without tissue coring. In both cases, the edges of the metal tubular shaft 22 may be rounded to provide an atraumatic tip. The distal port 36 may face distally as shown or may face laterally as described previously. The relative stiffness of the metallic tubular shaft 22 facilitates easy insertion through the heart wall, optionally negating the need for a separate introducer sheath.

[0062] In addition to distal port 36, a more proximal filling port 31 may be utilized to facilitate filling the lumen 24 of the tubular shaft 22 with the fill fluid. Fluid may be introduced into filling port 31 utilizing a needle and syringe to inject fluid, or a vacuum may be applied to the port 31 to pull fluid in through distal port 36. The filling port 31 may be covered my a self-sealing septum or membrane, or may be closed off subsequent to filling by utilizing a suitable adhesive, preferably at body temperature to minimize pressure offset at in-vivo temperatures.

[0063] With reference to Figure 5Q, the inside diameter of the tubular shaft 22 may be increased near the distal end of the PTC 34 without increasing the outside diameter. The increased inside diameter and thinner wall at the distal end of the tubular shaft 22 improves pressure transmission while the low profile defined by the outside diameter reduces adverse effects on blood flow and tissue trauma at the insertion site.

[0064] With reference to Figure 5R, the distal end of the tubular shaft 22 is flared in the shape of a bugle. The bugle-shaped tip allows the gel plug 26 to be initially recessed before implantation to protect it from disruption. Upon heating from room or storage temperature to body temperature, the relatively lower thermal expansion of the tubular shaft 22 as compared to the fluid 24 and gel 26 effectively deploys or displaces the gel

plug 26 distally thus minimizing any remaining recess that may otherwise permit blood pooling. The bugle shape also reduces the likelihood of displacement of the gel plug 26 beyond the distal end of the PTC 34 due to excessively high temperatures sometimes encountered during shipment and storage.

[0065] With reference to Figure 5S – 5U, various closed-end embodiments of the PTC 34 are shown. In each of these embodiments, the distal port 36 is eliminated in favor of a thin membrane 28, thus eliminating the need for gel plug 26 to hold the fill fluid 24 in the PTC 34. However, it is also contemplated that the membrane 28 may be used in conjunction with the gel plug 26 to prevent wash-out of the gel plug 26.

[0066] The thin membrane 28 may comprise an integral part of the tubular shaft 22 as shown in Figure 5S, or an additional tubular component as shown in Figures 5T and 5U, which may be fixed to the tubular shaft 22 by a suitable adhesive and/or a compression ring disposed around the membrane 28 and tubular shaft 22 near the proximal end of the PTC 34. Alternatively, the thin membrane 28 may comprise an additional end-cap component which may be sealed to the distal rim of the tubular shaft 22. In each instance, the thin membrane 28 may be mounted tightly or loosely to tune the membrane 28 to the desired frequency response and minimize the degree of hysteresis.

[0067] The membrane 28 may be formed of a thin biocompatible polymeric material such as ePTFE, PU, or PET, for example. Alternative materials include Hyaluronic acid, Manitol (or other sugar alcohols, PEG, PLA), PVA (water soluble), Parylene, silicone material (gel, elastomer, etc.), silicone/urethane composite elastomers, and urethane elastomers. The membrane 28 may be separately formed by extrusion, deposition or molding techniques, for example, and subsequently attached to the tubular shaft 22 of the PTC 34. Alternatively, the membrane 28 may be formed directly on the tubular shaft 22 of the PTC 34 by chemical vapor deposition, sputter coating, dip coating, electron beam deposition, or another thin film deposition process.

[0068] In these closed-end embodiments, variations in thermal expansion may be dealt with in a manner different than in prior embodiments that permit displacement of the gel plug to equilibrate pressure in the PTC 34. In the closed-end embodiments, a gas pocket may be disposed in the PTC 34, which may be vented prior to use. To vent the gas pocket and maintain a liquid barrier, the membrane 28 may be may be porous, a small bore vent tube (not shown) may be temporarily disposed through the membrane, a vent hole 21 may

be provided in the membrane 28, or a fill port 31 as described previously may be employed to permit venting and accommodate variations in thermal expansion of the fill fluid 24. In each of these venting mechanisms, the pore or hole size may be selected to permit passage of gas but not liquid. After implantation, the venting mechanism may occlude naturally due to impregnation of cellular structures and endothelialization.

[0069] With reference to Figure 5V, this embodiment of the PTC 34 incorporates circular ridges 23 spaced apart along the tubular shaft 22. The circular ridges 23 are sized and spaced to effectively capture the heart wall when the PTC 34 is inserted therethrough. The ridges 23 may be integrally formed with the tubular shaft 22 or may be separately formed and thereafter bonded to the tubular shaft 22. The circular ridges may be used in place of or in addition to other means (e.g., sutures) for securing the RSA 30 to the heart wall. This embodiment is particularly useful for septal wall anchoring where surgical access is more difficult making sutures difficult to place.

[0070] With reference to Figure 5W, additional flexibility may be imparted into the PTC 34 by forming the tubular shaft 22 in the form of a helix. This may be particularly desirable if a metallic tubular shaft 22 is used, such as stainless steel, titanium, or nickel titanium, for example. A flare may be imparted into the distal end of the tubular shaft 22 to reduce motion and thermal artifact as described previously, or the distal opening 36 may be counter-bored (as shown) to a larger inside diameter to have a similar effect.

[0071] In any of the foregoing embodiments of the PTC 34, particularly the closed-end embodiments described with reference to Figures 5S – 5U, the cross-sectional shape of the lumen 24 of tubular shaft 22 may be non-circular to define thinner wall areas for enhanced pressure transfer to the fill fluid. An example of a tubular shaft 22 with a uniform wall is shown in Figure 6A, and examples of tubes 22 with non-uniform walls are shown in Figures 6B – 6D. In each embodiment, the outside profile of the tubular shaft 22 may be circular. In Figure 6B, the inner lumen 24 has an oval cross-section to generally define two areas with thinner walls. In Figures 6C and 6D, the inner lumen 24 has a polygonal cross-section to generally define a plurality of alternating thin and thick wall areas. By maintaining some areas with thicker walls, the structural integrity and in particular the column strength of the PTC 34 may be substantially maintained.

[0072] With reference to Figures 7A – 7E and 8, various devices used to facilitate insertion of the PTC 34 through the heart wall are shown. These devices include sheath

retainers 710 and 720, introducer sheath 810 and trocar 820. The sheath retainers 710/720 may be used interchangeably or in combination. The sheath retainers 710/720 and trocar 820 may be formed of biocompatible metallic material (e.g., stainless steel), and the introducer sheath may be formed of a medical grade polymeric material (e.g., HDPE, PTFE). Conventional materials and manufacturing techniques may be employed, and various dimensions may be used as a function of the particular implant procedure.

[0073] In Figures 7A and 7B, side views of sheath retainers 710 and 720 are schematically shown. Both sheath retainers 710 and 720 include a base plate 712 connected to a handle 716 by a shaft 714. Sheath retainer 720 includes a top plate 722 connected to base plate 712 by bar 724, whereas tool 710 does not. A bottom view of base plate 712 is schematically shown in Figure 7C, and an alternative design is shown in Figure 7D. Base plate 712 includes a tapered slot 718, the narrower part of which is sized to slidably accommodate the introducer sheath 810. A top view of top plate 722 is schematically shown in Figure 7E. Top plate 722 includes a wide slot 728 that permits visualization of the RSA 30 therethrough, but is slightly narrower than the RSA housing 32. The connection bar 724 is slightly taller than the RSA housing 32, thereby holding the RSA 30 between the base plate 712 and the top plate 722 with the PTC 34 extending downward through the narrow slot 718.

[0074] In Figure 8, a side view of a trocar 820 disposed in a slit-sheath introducer 810 is shown. The introducer 810 includes a tubular sheath 812 with a longitudinal seam 816 that preferentially splits the sheath 812 into two parts when peeled. The sheath 812 is peeled around the RSA 30 by pulling on handles 814 connected to each side of the peelable sheath 812. The trocar 820 includes a sharpened distal tip 822 for penetrating the heart wall. A handle 824 is connected to the proximal end of the trocar 820 to facilitate manual removal of the trocar 820 from the introducer 810 once the heart wall has been pierced.

[0075] In use, the trocar 820 may be initially disposed in the introducer 810 as shown in Figure 8, and both may be advanced as a unit through the heart wall. Once the heart wall is pierced, and the distal end of the introducer sheath 810 resides in the desired heart chamber, the trocar 820 may be removed from the introducer 810. The PTC 34 may then be inserted into the lumen of the introducer sheath 810 until the housing of the RSA rests adjacent the epicardial surface and the PTC 34 resides in the desired heart chamber. The

sheath retainer 710 or 720 may then be positioned by sliding the base plate 712 around the introducer 810 such that the tubular sheath 812 resides in the slot 718 and the base plate 712 resides adjacent the epicardial surface. While holding the RSA 30 in place (either manually or with tool 720), and while holding the base plate 712 firmly against the epicardial surface, the introducer sheath 810 may be removed by pulling on handles 814 and peeling the sheath 812 around the RSA 30.

[0076] The various embodiments of the PTC 34 described herein refer pressure from the tip of the PTC 34 to a pressure sensor 39 via a gel, a gel/fluid combination, a fluid/membrane combination, or a fluid/balloon combination, which generally transfers a high fidelity signal from the tip of the PTC 34 to the pressure sensor 39 in order to obtain a highly accurate reproduction of the pressure waveform. The high fidelity transmission aspect often means that the pressure signal contains high frequency components. The presence of high frequencies in the pressure signal requires that the pressure signal be sampled at a rate high enough to avoid artifact from aliasing. The pressure sensor employed with the PTC 34 may be sampled at discrete times, such that power is applied to the sensor only when a measurement is desired. This results is reduced power consumption compared to continuously applying power. The required sampling rate may be about 3 - 5 times the highest significant frequency component present in the pressure signal, as defined by the Nyquist criteria and practical limitation of discrete sampling of signals. Since power is applied to the sensor only during sampling, minimizing the sampling rate reduces power consumption.

[0077] To further reduce power consumption, and thereby increase battery longevity, various aspect of the PTC 34 may be modified to optimize this effect. For example, by reducing the required sampling frequency, the power consumption may also be reduced. To achieve this effect, certain properties of the PTC 34 and the medium employed within the PTC 34 to transfer the pressure signal may be designed to filter out higher frequency components of the pressure signal to thereby reduce frequency response. By filtering out higher frequencies with the PTC 34, the sampling rate on the sensor can be reduced without introducing artifact from aliasing.

[0078] There are a number of approaches that can be taken to reduce the frequency response of the catheter. These include, by way of example, not limitation, reducing the lumen diameter of the PTC 34, increasing the viscosity of the fluid in the lumen of the

PTC 34, increasing the length of the portion of the PTC 34 containing the gel, filling the whole length of the PTC 34 with gel, increasing the viscosity of the gel, increasing the length of the PTC 34, and increasing the compliance of the PTC 34 and/or the pressure sensor. Increasing the viscosity of the gel and lengthening of the gel may reduce the ability of the gel to compensate for changes in PTC lumen volume during bending and thermal expansion and contraction and therefore may not be as desirable as other approaches. Although changing catheter length may be a viable approach, length is often impacted by other factors and cannot be varied, such as anatomical requirements. Lumen diameter and gel length may often prove to be the most practical, straight forward, and reliable approaches to affecting frequency response.

[0079] Reducing the frequency response of the PTC 34 may provide benefit whenever there are features in the pressure waveform that do not provide significant value relative to the need for reduced power consumption of the pressure sensing system. One example is when the system is used to monitor left atrial (LA) pressure. In patients with mitral regurgitation, small deflections in LA pressure occur during each cardiac cycle that contain higher frequencies. However, many physicians to not believe there is significant diagnostic value in monitoring these small perturbations and that average LA pressure provides the most important information.

[0080] There are many situations where power consumption is very important for a pressure sensing system, such as with the implantable pressure sensing system as described herein. For example, an increase of current drain by 2 uA results in a decrease in battery life of most implantable defibrillators by 6 months. It is therefore desirable to reduce power consumption and increase battery life. For example, when measuring LA pressure, most physicians agree that the average pressure provides the vast majority of the value, and this approach could reduce the required sampling rate from 500 Hz to 10 Hz or less, resulting in a considerable power savings.

[0081] Thus, for some clinical applications, the PTC 34 may act as a low-pass filter to effectively filter out frequencies that add little clinical value. Depending on the clinical application, the PTC 34 may filter out frequencies above 50 Hz, 10 Hz, 5 Hz, or 1 Hz, and correspondingly reduce the required sampling rate and thereby increase battery longevity.

[0082] This approach may also be useful as an "antialiasing filter". As an antialiasing filter, applying these concepts may result in the removal of higher frequency non-essential

frequency components that can result in aliasing of the pressure signal. These components could be present in the pressure signal from turbulent flow and other perturbations on the pressure waveform that have little or no clinical utility. Aliasing from these factors could be prevented by increasing the sampling rate, but may result in higher power consumption, thus low-pass filtering may be preferable.

[0083] To illustrate the effect of various PTC 34 design parameters on low-pass filtering to achieve the objectives set forth above, a mathematical model may be employed. Using an electrical circuit as an analog model of a mechanical system as shown in Figure 9, and solving for the unknown parameters using differential equations and other techniques known to those skilled in the art, the various design parameters may be adjusted to achieve the low-pass filtering effect. In this model, which is one example of a plurality of models that may be used, the components of the circuit represent the mechanical system as follows. The fill-fluid 24 and gel 26 are treated as lumped parameters distributed along the length of the tubular shaft 22, with separate resistance and inertance. A first capacitor is used to represent compliance of the tubular shaft 22. The nipple tube 38 is assumed to be non-compliant (stainless steel), and is therefore modeled as separate resistance and inertance. A second capacitor is used to represent the diaphragm of the pressure transducer.

[0084] The frequency response characteristics of the PTC/sensor system can be varied at will by adjusting one or more of the following list of parameters: length of the catheter; length of the gel plug; length of the nipple tube; inner diameter of the catheter; outer diameter of the catheter; inner diameter of the tip; outer diameter of the tip; inner diameter of the nipple tube; viscosity of the fill fluid; viscosity of the gel; specific gravity of the fill fluid; specific gravity of the gel; elastic modulus of the polymer used to make the catheter; and/or pressure compliance of the sensor.

[0085] A typical frequency response curve for such a system is shown in Figure 10. The figure plots the ratio Po/Pi as a function of the frequency of the pressure pulsation (in Hz). The pressure Po is the amplitude of the sinusoidal pressure on the "output" side of the catheter (i.e., the pressure amplitude acting on the sensor). The pressure Pi is the amplitude of the sinusoidal pressure acting on the "input" side of the catheter (i.e., on the exposed surface of the gel plug). At low frequencies, the ratio is 1.0. Thus, the output and input amplitudes are identical. At higher frequencies, the ratio exhibits a sharp decline

with increasing frequency. The "half-power point" is defined as that frequency at which the ratio Po/Pi is equal to 0.707. This is the frequency at which the amplitude ratio has decreased by 3 dB from its low-frequency asymptote. In the case shown in Figure 1, the half-power frequency is close to 5 Hz.

[0086] By manipulating one or more of the design parameters listed above, the half-power frequency can be tailored to suit any given physiological application. If it is desired that the catheter/sensor system act as a low-pass filter (allow only low frequencies to go from input to output), then the half-power point can be adjusted to a suitably low value. Conversely, if the catheter is required to track high frequency pulsations, the half-power frequency may be tailored to an appropriately high value.

[0087] Five cases are presented by way of example, not limitation, to illustrate how a desired frequency response can be achieved by varying several of the design parameters while satisfying design requirements imposed by the intended application. These five cases are summarized in Table 1 as shown in Figure 11. In each of these cases, the half-power frequency is close to 5 Hz.

[0088] Case 1 may be considered to be a "baseline" case. The variations from the baseline, and the rationale for the variations presented, is described below.

[0089] Case 2: Slightly longer catheter; higher elastic modulus of polymer to maintain bend stiffness.

[0090] Case 3: Straight catheter without flared tip; length and elastic modulus as in Case 1. Gel and fill fluid viscosity are changed to obtain desired frequency response.

[0091] Case 4: Straight catheter without flared tip. Smaller diameter than in Case 3. Length same as in Case 1. Elastic modulus is increased to maintain bend stiffness. Gel viscosity of 25000 cP needed to obtain desired frequency response.

[0092] Case 5: Straight catheter, smaller diameter than in Case 3, longer than in Case 3. Elastic modulus substantially higher than in Case 3 to maintain bend stiffness. Gel viscosity of 18000 cP obtains the desired frequency response.

[0093] From this model and these illustrations, it will be appreciated that the PTC 34 and its associated components may be modified to have the desired filtering effect in order

to achieve lower power consumption, antialiasing, or other objectives not specifically mentioned herein.

[0094] From the foregoing, it will be apparent to those skilled in the art that the present invention provides, in exemplary no-limiting embodiments, a wide variety of design options for pressure transmission catheters, particularly adapted for use with implantable pressure sensing devices. Further, those skilled in the art will recognize that the present invention may be manifested in a variety of forms other than the specific embodiments described and contemplated herein. Accordingly, departures in form and detail may be made without departing from the scope and spirit of the present invention as described in the appended claims.